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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/068,227 05/05/98 WAKI

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EXAMINER

MCCLENDON, S

ART UNIT	PAPER NUMBER
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1711

DATE MAILED:

06/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/068,227</b>	Applicant(s) <b>Waki et al</b>
	Examiner <b>Sanza McClendon</b>	Group Art Unit <b>1711</b>

Responsive to communication(s) filed on May 5, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) 17 and 18 is/are withdrawn from consideration.

Claim(s) 10 and 14 is/are allowed.

Claim(s) 1-5, 8, 9, 12, 13, 16, and 20 is/are rejected.

Claim(s) 6, 7, 11, 15, and 19 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**DETAILED ACTION**

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 19-20, drawn to photo cured hyaluronic acid gel.

Group II, claim(s) 17-18, drawn to a biomedical material kit.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the biomedical material kit does not require the photo cured hyaluronic acid gel as specified by the limitations of claims 1-16 of Group I.

3. During a telephone conversation with Louis Grubinsky on June 2, 1999 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16 and 19-20. Affirmation of this election must be made by applicant in replying to this Office action.

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1       Claims 17-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b),  
2       as being drawn to a non-elected invention.

3       4.       Applicant is reminded that upon the cancellation of claims to a non-elected invention,  
4       the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the  
5       currently named inventors is no longer an inventor of at least one claim remaining in the  
6       application. Any amendment of inventorship must be accompanied by a petition under 37  
7       CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

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9

10       *Claim Objections*

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12       5.       Claims 6, 7, 11,15 and 19 are objected to under 37 CFR 1.75© as being in improper  
13       form because a multiple dependent claim cannot depend on another multiple dependent  
14       claim. See MPEP § 608.01(n). Accordingly, the claims 6, 7, 11, 15, and 19 have not been  
15       further treated on the merits.

16

17

18       *Claim Rejections - 35 U.S.C. § 102/35 U.S.C. § 103*

19

20       6.       The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form  
21       the basis for the rejections under this section made in this Office action:

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1           A person shall be entitled to a patent unless --

2           (b) the invention was patented or described in a printed publication in this or a foreign country or in public  
3           use or on sale in this country, more than one year prior to the date of application for patent in the United  
4           States.

5           7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
6           obviousness rejections set forth in this Office action:

7           (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth  
8           in section 102 of this title, if the differences between the subject matter sought to be patented and the prior  
9           art are such that the subject matter as a whole would have been obvious at the time the invention was made  
10           to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be  
11           negated by the manner in which the invention was made.

12  
13           8. Claims 1-6, 9-10, 12- 13, and 16 are rejected under 35 U.S.C. 102(b) as anticipated by  
14           or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsuda et al (EP 0 554 898  
15           A2).

16           Matsuda et al discloses a photo curable glycosaminoglycan derivative (photo curable  
17           GAG) which comprises a GAG and a photo reactive compound bound thereto and a cross  
18           linked GAG prepared by subjecting the photo curable GAG to cross linking reaction with the  
19           photo reactive compound.

20           Matsuda et al teaches that the GAG includes colominic acid, hydraluronic acid, and  
21           others listed on page 10 lines 35-39. These should have a molecular weight range from 4,000  
22           to 2,000,000. This appears to read on the hydraluronic acid in the claimed invention.  
23           However, in the alternative, it would have been obvious to one of ordinary skill in the art to  
24           use hydraluronic acid with the expectation of obtaining a useful coating composition in the  
25           absence of unexpected results.

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1 Matsuda et al teaches that the photo reactive group may be any group provided that  
2 it is capable of at least dimerizing inter-molecularly and/or intra molecularly upon exposure  
3 to light under formation of a cyclobutane ring--page 7, lines 55 to end. Matsuda et al teaches  
4 that cinnamic acid can be used as the photo reactive group among others. This appears to  
5 read on the limitations of the claimed invention. However, in the alternative, it would have  
6 been obvious to use cinnamic acid as the photo reactive cross linker as taught by Matsuda  
7 et al with the expectation of an adequately cross linked GAG in the absence of unexpected  
8 results. Matsuda et al teaches that the photo cured GAG can have a degree of  
9 substitution (DS) preferably between about 0.1 to 0.5 when used as a tissue nonadhesive  
10 material. This reads on the limitation of claim 2 and the tissue non-adhesive reads on the  
11 limitation of claim 16. Matsuda et al also teaches that when hydraluronic acid is used that  
12 the DS be between about 0.1 to 3.0. This range appears to read on the limitation of claim 2.  
13 However, in the alternative, it would have been obvious to provide a DS between about 0.1  
14 to 0.5 as taught by Matsuda et al with the expectation of a useful tissue nonadhesive in the  
15 absence of unexpected results.

16 Matsuda et al teaches that the photo reactive compound (cinnamic acid) can be bound  
17 to GAG or to a spacer group. Matsuda et al teaches that the spacer groups can be basic  
18 amino acids--page 12-- and amino alcohols on page 5, line 50 with a formula\* representation  
19 on page 7, line 15 when R3 is  $(CH_2)_n$  and n is 2. This appears to read on claim 5. However,  
20 in the alternative, it would be obvious to one of ordinary skill in the art to use a amino acid  
21 or amino alcohol spacer group as taught by Matsuda with the expectation of adequate results

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1 in the absence of any unexpected results. Matsuda et al teaches that when basic amino acids  
2 are used as spacers the GAG is used in aqueous solution and the two are subjected to an  
3 amidation reaction in the presence of a condensing agent.

4 Matsuda et al teaches that the photo curable GAG is found in concentrations of  
5 amounts from 1 to 30%--page 16. This appears to read on claim 12. However, in the  
6 alternative, it would have been obvious to one of ordinary skill in the art to use concentration  
7 from 0.5 to 10% as encompassed in the concentration from about 1 to 30% with the  
8 expectation of adequate results in the absence of any unexpected results. Matsuda et al  
9 teaches that the photo curable GAG can be irradiated using UV radiation in the range of 260  
10 to 400 nm. This appears read on the UV irradiation limitation of claim 8. In Example 1,  
11 Matsuda et al teaches that the solution of the photo curable GAG was heat sterilized before  
12 photo curing with the photo reactive group. This anticipates claim 13. In Example 12,  
13 Matsuda et al teaches that the cross linking reaction can be under heating vs. photo initiation.  
14 This anticipates claim 9.

15 Matsuda et al teaches that contact angles are increased as the DS is increased. And  
16 the an increase in contact angle reflects an increase in film surface hydrophobicity. It is the  
17 examiner's understanding that as the DS increases the contact angle increases and the  
18 hydrophobicity increase or i.e., the water absorption decreases. In example 15, Matsuda et  
19 al discloses swelling capacities that appear to read on the limitations of claim 3. However,  
20 in the alternative, one of ordinary skill in the art would be able to adjust the water absorption  
21 (swelling capacity) by adjusting the DS as taught by Matsuda et al to obtain a hydrophilic or

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1 hydrophobic photo curable cross linked hydaluronic acid as taught by Matsuda et al in the  
2 absence of unexpected results.

3 It is the examiner's contention, that the photocrosslinked-GAG of Matsuda et al is  
4 anticipated by and/or in the alternative obvious over the claimed invention. Therefore, the  
5 photo cured cross linked-hydraluronic acid gel of Matsuda et al would inherently contain a  
6 storage modulus ( $G'$ ) of from 50 to 1500 Pa, a loss modulus ( $G''$ ) of from 10 to 300 Pa, and  
7 a tangent delta ( $G''/G'$ ) of from 0.1 to 0.8 in dynamic visocelasticity measured by a rheometer  
8 under the conditions of claims 1 and 8-9. The claimed invention is read in the  
9 reference.

10 \* It is noted that these disclosures anticipate and/or obvious over objected claims that have  
11 not been further treated on merits.

12

13 *Claim Rejections - 35 U.S.C. § 103*

14

15 9. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda  
16 et al (EP 0 554 898 A1).

17 Matsuda et al is disclosed in the above rejection. Matsuda et al teaches that the photo  
18 cured GAG can be used for medical applications. They can be used in various forms, such  
19 as solutions, gels, solid, etc. Matsuda et al also teaches that they can be used as controlled  
20 drug release materials. In which, they can be prepared into tablets by compression molding  
21 in, or preparing powders, granules, etc., they can be molded into films, or immobilized on

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1 some other support, they can have ophthalmic preparation, prepared for embedding into  
2 living bodies, or prepared to be inserted in to body cavities. Matsuda et al does not expressly  
3 disclose a container in which a gel can be push out for injection. However, Matsuda et al  
4 teaches that the photo curable cross linked GAG can be made into a gel and that it can be  
5 prepared to be embedded into living bodies. Therefore, it is the examiner's contention, that  
6 it would have been obvious for one of ordinary skill in the art to use a container the can  
7 embed objects or insert object. Thus the claimed invention is read in the reference.

8

9 *Allowable Subject Matter*

10

11 10. Claims 10 and 14 are objected to as being dependent upon a rejected base claim, but  
12 would be allowable if rewritten in independent form including all of the limitations of the  
13 base claim and any intervening claims.

14 *Conclusion*

15

16 11. The prior art made of record and not relied upon is considered pertinent to applicant's  
17 disclosure. US Patent 5,700,848 to Soon-Shiong et al. US Patent 5,462,976 which is  
18 equivalent to EP 0 554 898 A1.

19 12. Any inquiry concerning this communication or earlier communications from the  
20 examiner should be directed to Sanza McClendon whose telephone number is (703)305-0505.  
21 The examiner can normally be reached from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck, can be reached at (703) 308-2462.

3 Any inquiry of a general nature or relating to the status of this application or  
4 proceeding should be directed to the receptionist whose telephone number is (703) 308 -1495.

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James J. Seidleck  
Supervisory Patent Examiner  
Technology Center 1700

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smc

June 2, 1999